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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,544	03/17/2004	Kazuhisa Fukushima	042187	2323

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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
01/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/801,544	FUKUSHIMA, KAZUHISA	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02 October 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 06 October 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-3, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 3,567,611 (Michel et al.) in view of US Patent Application Publication 2002/0058273 A1 (Shipwash), 2002/0155032 A1 (Liu et al.), US Patent Application Publication 2003/0027354 A1 (Geli), and US Patent Application Publication 2006/0127942 A1 (Straume et al.).

5. For purposes of examination, the method of claims 1 and 2 have been construed as optionally further comprising a step of performing magnetophoresis.

6. Michel et al., column 1, state:

> The invention relates to partitioning techniques and refers more specifically to a method of partitioning human normal serum protein or the like by two-stage electromagnetophoresis as a function of molecular paramagnetism in which a material sample is electrophoresed and then magnetophoresed to provide displacement and grouping of molecules in accordance with their physical and electrical properties.

7. Michel et al., column 2, teach that the separation medium (applicant's partition) is a polyacrylamide gel. Such a showing meets a limitation of claims 3 and 8.

8. Michel et al., column 2, disclose the protein being placed (applicant's injected) into a depression on one surface of the gel.

9. Michel et al., do not teach using a device that comprises multiple solutions, pillars nor does Michel et al. teach "injecting" the target biopolymer into a solution.

10. Shipwash, paragraph [306], disclose performing 2-dimensional electrophoresis on a chip whereby proteins are isolated.

11. Liu et al., abstract, disclose performing electrophoresis of nucleic acids whereby a sample is "injected" into a solution present in a sample channel.

12. Liu et al., paragraph [0030], teach that a volume of sample is introduced into a sample channel. Such a showing is considered to meet a limitation of applicant's first solution.

13. Liu et al., paragraph [0032], teach that the device can be used in a method of continuous separation whereby three blocks (applicant's partition) are employed. The aspect of using three blocks speaks to three solutions and at least one partition.

14. Liu et al., paragraph [0033], disclose injecting fixed volumes of sample.

15. Liu et al., paragraph [0011] teach that a wide variety of molecules can be isolated via capillary electrophoresis. Specifically identified are proteins and nucleic acids.

16. Geli disclose a method and related device for separating biopolymers via electrophoresis. As seen in paragraph [0059], the device comprises an inlet port as well as an evacuation outlet, thereby allowing for the recovery and preservation of the isolated biopolymer.

17. Geli, paragraph [0191], discloses using "polymeric monoliths micro-rods" that are "appropriate for protein separation." Such a showing is deemed to meet the limitation of a "pillar array" as found in claims 3 and 8.

18. Neither Michel et al., Shipwash, Liu et al., nor Geli teach using magnetic beads (limitation of claims 7 and 8)

19. Straume et al., teach at length how magnetic beads can be coupled to any of a variety of biopolymers, including nucleic acids and proteins, and can be used to separate the bound biopolymer from other components in a sample.

20. Straume et al., page 12, disclose the use of beads in an electrophoretic medium, and that the beads can be coupled to nucleic acids.

21. Paragraph [0126] teaches that magnetic beads, when coupled to DNA, are able to move through a medium in response to electrophoretic force.

22. Straume et al., page 13, bridging to page 14, teaches separation of DNA from magnetic beads.

23. In view of the continued importance of separating biopolymers such as nuclei acids and proteins via electrophoresis (one dimensional or two-dimensional) as well as including magnetophoresis to further purify the biopolymer of interest, one of ordinary skill in the art at the time the invention was made would have been amply motivated to have modified the method of Michel et al., by combining the option of performing two-dimensional electrophoresis of Shipwash and further combining the aspect of sample injection (Liu et al.) as well as optionally using a pillar array (Geli) or gel (Michel et al., Shipwash) to effect separation of the biopolymer of interest. It would have also been obvious to one of ordinary skill in the art at the time of the invention to have employed the use of magnetic beads as disclosed by Straume et al., as such would have significantly enhanced the magnetic properties of nucleic acids bound thereto, and thereby enhanced the sensitivity and efficiency of the assay.

24. In view of the explicit guidance that the disclosed methods are applicable to proteins and/or nucleic acids, said ordinary artisan would have had a most reasonable expectation of success.

25. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-3, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 3,567,611 (Michel et al.) in view of US Patent Application Publication 2002/0058273 A1 (Shipwash), 2002/0155032 A1 (Liu et al.), US Patent Application Publication 2003/0027354 A1 (Geli) and US Patent Application Publication 2006/0127942 (Straume et al.).

Conclusion

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner, Art Unit 1634